UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): May 4, 2022

BEIGENE, LTD.

(Exact Name of Registrant as Specified in Charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

c/o Mourant Governance Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands
(Address of Principal Executive Offices) (Zip Code)

+1 (345) 949-4123
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

*Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 5, 2022, BeiGene, Ltd. (the "Company") announced its financial results for the three months ended March 31, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01. Other Events.

In its press release dated May 5, 2022, the Company also provided an update on the first quarter of 2022 and recent business highlights and expected milestones for the remainder of 2022 and 2023. The information in the press release set forth under the headings "Recent Business Highlights", "Expected Milestones" and "Forward-Looking Statements" is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

On May 4, 2022, the Company issued a press release announcing that the China National Medical Products Administration granted conditional approval of BLINCYTO® (blinatumomab) for injection for the treatment of pediatric patients with relapsed or refractory (R/R) CD19-positive B-cell precursor acute lymphoblastic leukemia. A copy of this press release is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release titled "BeiGene Reports First Quarter 2022 Financial Results" issued by BeiGene, Ltd. on May 5, 2022
99.2	Press release titled "BeiGene Announces the Approval in China of BLINCYTO (Blinatumomab) for Injection for Pediatric Patients with Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)" issued by BeiGene, Ltd. on May 4, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BEIGENE, LTD.

Date: May 5, 2022

By: /s/ Scott A. Samuels
Name: Scott A. Samuels
Title: Senior Vice President, General Counsel

BeiGene Reports First Quarter 2022 Financial Results

- *Recorded product revenue of $261.6 million for the first quarter, representing a 146% increase from $106.1 million in the prior year period*
- *BRUKINSA product revenue increased 372% globally versus the first quarter of 2021, led by growth in U.S. and China*
- *New global clinical data support FDA and EMA filings under review, including ALPINE trial of BRUKINSA versus ibrutinib in chronic lymphocytic leukemia*
- *Positive interim analysis of RATIONALE-306 study of tislelizumab in combination with chemotherapy in esophageal squamous cell carcinoma showed statistically significant and clinically meaningful improvement in overall survival*
- *Held groundbreaking for flagship U.S. manufacturing and clinical R&D facility in Hopewell, N.J.*

CAMBRIDGE, Mass., BASEL, Switzerland and BEIJING, China, May 5, 2022 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today reported financial results for the first quarter of 2022, recent business highlights, and anticipated upcoming milestones.

“I have never been more confident in BeiGene. We made terrific progress in the first quarter with our global commercial performance in the U.S., Europe, and in Asia, and we continue to build on our strategic competitive advantages, including breaking ground on our flagship U.S. manufacturing and clinical R&D campus at Princeton Innovation West in Hopewell, N.J.,” said John V. Oyler, Co-Founder, Chairman, and CEO at BeiGene. “BRUKINSA and tislelizumab continue to validate our ability to run global clinical trials and bring impactful medicines to cancer patients. We announced long-term follow up data from our Phase 3 head-to-head global ALPINE trial in relapsed/refractory CLL, where BRUKINSA demonstrated superiority in overall response rate versus ibrutinib as assessed by an Independent Review Committee and continued to show lower rates of atrial fibrillation and flutter. Our tislelizumab program with Novartis has also progressed with positive data from RATIONALE 306, our global trial in 1L advanced esophageal cancer. We are well positioned to advance our pipeline and expand our global capabilities to meet the needs of patients around the world.”

Julia Wang, Chief Financial Officer, commented, “During the first quarter we saw product revenue grow meaningfully across our commercial portfolio and geographies, led by internally developed medicines, and we expect continued momentum based on approvals secured to date and upcoming milestones. We are well positioned financially with our strong capital position and look forward to our multiple upcoming catalysts.”

First Quarter 2022 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $6.3 billion as of March 31, 2022, compared to $6.6 billion as of December 31, 2021.

- In the three months ended March 31, 2022, cash used in operating activities was $236.6 million, primarily due to our net loss of $434.3 million, offset by a decrease in our net operating assets and liabilities of $122.1 million and by non-cash charges of $75.6 million; capital expenditures were $45.1 million; and cash used in financing activities was $11.3 million.

Revenue for the three months ended March 31, 2022 was $306.6 million, compared to $605.9 million in the same period of 2021.

- Product revenue totaled $261.6 million for the three months ended March 31, 2022, compared to $106.1 million in the same period of 2021, including:
  - Global sales of BRUKINSA of $104.3 million for the first quarter of 2022, compared to $22.1 million in the prior year period;
  - Sales of tislelizumab in China of $87.6 million for the first quarter of 2022, compared to $48.9 million in the prior year period;
  - Sales of Amgen in-licensed products in China of $29.9 million for the first quarter of 2022, compared to $14.5 million in the prior year period. Prior year period sales do not include sales of BLINCYTO® and KYPROLIS®, which were launched in China in August 2021 and January 2022, respectively; and

  - Sales of BMS in-licensed products in China of $27.2 million for the first quarter of 2022, compared to $20.3 million in the prior year period.

- Collaboration revenue for the three months ended March 31, 2022 was $45.1 million, resulting from partial recognition of the upfront payments from Novartis of $650.0 million related to the tislelizumab agreement and $300.0 million related to the ociperlimab agreement, which were entered into in the first quarter and fourth quarter of 2021, respectively. Collaboration revenue for the three months ended March 31, 2021 was $499.8 million, resulting from the recognition of revenue of a significant portion of the upfront payment from Novartis related to the tislelizumab agreement.

Expenses for the three months ended March 31, 2022 were $749.9 million, compared to $535.7 million in the same period of 2021.

- **Cost of Sales** for the three months ended March 31, 2022 were $65.2 million, compared to $32.7 million in the same period of 2021. Cost of sales increased primarily due to increased product sales of tislelizumab and BRUKINSA, as well as BLYNCYTO, which commenced in August 2021.

- **R&D Expenses** for the three months ended March 31, 2022 were $389.9 million, compared to $320.7 million in the same period of 2021. The increase in R&D expenses was primarily attributable to increases in headcount and costs related to investment in our discovery and development activities, including our continued efforts to internalize research and clinical development activities, partially offset by lower fees paid to external CROs on clinical trials for tislelizumab, as well as decreased expense related to upfront fees for in-process R&D. Upfront fees related to in-process R&D for in-licensed assets totaled nil and $8.5 million in the first quarters of 2022 and 2021, respectively. Employee share-based compensation expense also contributed to the overall increase in R&D expenses and was $30.9 million for the three months ended March 31, 2022, compared to $21.9 million for the same period of 2021.

- **SG&A Expenses** for the three months ended March 31, 2022 were $294.6 million, compared to $182.1 million in the same period of 2021. The increase in SG&A expenses was primarily attributable to increased headcount, largely related to the expansion of our commercial teams, higher professional service fees and higher external commercial expenses, including selling and marketing, market access studies and promotional activities. The overall increase in SG&A expenses was also attributable to higher SG&A-related share-based compensation expense, which was $34.7 million and $23.9 million for the first quarters of 2022 and 2021, respectively.

- **Net Loss** for the quarter ended March 31, 2022 was $434.3 million, compared to net income of $66.5 million in the prior year period, primarily due to lower collaboration revenue. For the quarter ended March 31, 2022, net loss per share was or $0.33 per share, and $4.24 per American Depositary Share (ADS). For the quarter ended March 31, 2021, basic and diluted earnings per share were $0.06 and $0.05, respectively, and basic and diluted earnings per ADS were $0.73 and $0.69, respectively.

Recent Business Highlights

Commercial Operations

- Product sales increased 146% in the first quarter of 2022 compared to the prior year period, primarily due to increased sales of our internally developed products and in-licensed products from Amgen;

- Global sales of BRUKINSA totaled $104.3 million in the first quarter, representing a 372% increase compared to the prior year period. U.S. sales of BRUKINSA totaled $67.9 million in the first quarter, representing growth of 570% compared to the prior year period, driven by expanded uptake across all approved indications — mantle cell lymphoma (MCL), Waldenström's macroglobulinemia (WM) and marginal zone lymphoma (MZL). BRUKINSA sales in China totaled $33.5 million in the first quarter, representing growth of 180% compared to the prior year period, driven by a significant increase in all approved indications, including chronic lymphocytic leukemia (CLL);

- Sales of tislelizumab in China totaled $87.6 million in the first quarter, representing a 79% increase compared to the prior year period. In the first quarter, new patient demand from broader reimbursement in additional National Reimbursement Drug List (NRDL) approved indications continued to drive increased market penetration and market share for tislelizumab; and

- Completed transition and initiated marketing and promotion of five Novartis approved and nationally reimbursed oncology products in China's Broad Markets. These products include: TAFINLAR® (dabrafenib), MEKINIST® (trametinib), VOTRIENT® (pazopanib), AFINITOR® (everolimus), and ZYKADIA® (ceritinib).

Development Programs

BRUKINSA® (zanubrutinib)*, a small molecule inhibitor of Bruton's tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects, approved in 47 markets including the U.S., China, European Union (EU), Great Britain, Canada, Australia and South Korea in selected indications and under development for additional approvals globally. The global BRUKINSA development program includes nearly 4,000 subjects enrolled to-date in more than 25 countries and regions.*

- Announced additional results from the Phase 3 study ALPINE (NCT03734016) showing BRUKINSA demonstrated superiority versus ibrutinib in overall response rate as assessed by an Independent Review Committee (IRC) in patients with relapsed/refractory (R/R) CLL or small lymphocytic lymphoma (SLL). BRUKINSA was generally well tolerated with safety results consistent with previous studies; and
- Initiated patient enrollment for the Phase 3 study of zanubrutinib (NCT05100862) plus rituximab versus lenalidomide plus rituximab in patients with R/R MZL.

Tislelizumab*, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China in eight indications and under development for additional approvals globally. The global tislelizumab clinical development program includes more than 9,000 subjects enrolled to-date in more than 35 countries and regions.*

- Received approval in China for two new indications: advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, and in second-line esophageal squamous cell carcinoma (ESCC);
- Announced acceptance by the European Medicines Agency (EMA) of marketing authorization applications for tislelizumab for the treatment of patients with advanced or metastatic ESCC after prior chemotherapy and for patients with non-small cell lung cancers (NSCLC) including: as a monotherapy for the treatment of locally advanced or metastatic NSCLC after prior chemotherapy in adults; in combination with carboplatin and either paclitaxel or nab-paclitaxel for the first-line treatment of locally advanced or metastatic squamous NSCLC in adults; and in combination with pemetrexed and platinum-containing chemotherapy for the first-line treatment of locally advanced or metastatic non-squamous NSCLC in adults whose tumors have no EGFR or ALK positive mutations;
- Announced that the global Phase 3 RATIONALE 306 trial (NCT03783442) of tislelizumab in combination with chemotherapy met the primary endpoint of overall survival (OS) in patients with previously untreated advanced or metastatic ESCC at interim analysis;
- Presented updated results from the Phase 3 RATIONALE 309 trial (NCT03924986) of tislelizumab in first-line patients with nasopharyngeal cancer (NPC) at the Virtual American Society of Clinical Oncology (ASCO) Plenary Series, results will also be presented at the 2022 ASCO annual meeting;
- Presented clinical results and biomarker data on tislelizumab in solid tumors at the American Academy for Cancer Research (AACR) Annual Meeting, including the RATIONALE 303 (NCT03358875) and 304 (NCT03663205) Phase 3 studies evaluating tislelizumab in locally advanced or metastatic NSCLC; and
- Announced positive findings from interim analysis of the global Phase 3 RATIONALE 305 trial (NCT03777657) versus placebo in combination with chemotherapy as a first-line treatment for patients with locally advanced, unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with PD-L1 >5% expression. The study is continuing to final analysis.

Ociperlimab (BGB-A1217), *an investigational anti-TIGIT monoclonal antibody with competent Fc function. The global ociperlimab development program includes more than 25 countries and regions, and more than 1,000 subjects have been enrolled.*

- Entered strategic option, collaboration and license agreement with Novartis to develop, manufacture and commercialize ociperlimab in North America, Europe and Japan.

Early-Stage Programs

- Continued to advance our early-stage clinical pipeline of internally-developed product candidates at dose escalation stage, including:
  - BGB-A445: an investigational non-ligand competing OX40 monoclonal antibody as monotherapy or in combination with tislelizumab in solid tumors;
  - BGB-15025: an investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor as monotherapy or in combination with tislelizumab in solid tumors;
  - BGB-10188: an investigational PI3Kδ inhibitor as monotherapy or in combination with BRUKINSA in hematology malignancies, or in combination with tislelizumab in solid tumors; and
  - BGB-23339: a potent, allosteric investigational tyrosine kinase 2 (TYK2) inhibitor.
- Initiated patient dosing in the Phase 1 trial (NCT05006716) in patients with B-cell malignancies for BGB-16673 (an investigational Chimeric Degradation Activating Compound, or CDAC, targeting BTK).

Amgen Milestones

- Received conditional approval in China for BLINCYTO® (blinatumomab) for injection for the treatment of pediatric patients with R/R CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL). This approval was based on ex-China research data and Chinese adult data and full approval in this indication will depend on the results of a post-marketing study in China; and
- In collaboration with Amgen, launched KYPROLIS® (carfilzomib) for injection, a next-generation proteasome inhibitor, in China for patients with R/R multiple myeloma.

Zymeworks Milestones

- In collaboration with Zymeworks, completed enrollment in the global HERIZON-BTC-01 pivotal clinical trial (NCT04466891) evaluating the anti-tumor activity of zanidatamab monotherapy in patients with previously treated advanced or metastatic HER2-amplified biliary tract cancers (BTC), including gallbladder cancer and cholangiocarcinoma (bile duct cancer).

Bio-Thera Milestones

- Received approval in China for POBEVCY® in three new indications, including for the treatment of adult patients with recurrent glioblastoma; as a combination therapy with carboplatin and paclitaxel for the first-line treatment of stage III or IV epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer after primary surgical resection; and as a combination therapy with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of persistent, recurrent or metastatic cervix carcinoma.

Manufacturing Operations

- Held a groundbreaking for our flagship U.S. commercial-stage manufacturing and clinical R&D campus at the Princeton West Innovation Campus in Hopewell, N.J. Construction of the initial phase is expected to commence in 2022. The property has more than one million square feet of developable real estate for potential future expansion;
- Construction has started on our new small molecule manufacturing campus in Suzhou, China. Phase 1 of construction is expected to bring more than 52,000 square meters and expand production capacity to 600 million tablets/capsules and be completed in 2023. Once completed, qualified, and approved, the total production capacity is expected to increase our small molecule manufacturing capability in China by up to a total of ten times capacity; and
- Continued construction on our state-of-the-art biologics facility in Guangzhou, China, which currently is approved for 8,000 liters of biologics capacity, with an additional phase of construction to bring total capacity to 64,000 liters expected to be completed and GMP-ready by the end of 2022.

Corporate Developments

- Engaged Ernst & Young LLP based in Boston, Mass., as the principal auditor for our financial statements and internal control over financial reporting for the fiscal year ending December 31, 2022 to be filed with the SEC; and

- Published our 2021 Environmental, Social, and Governance (ESG) Report and introduced our **Change Is The Cure™** global ESG strategy that will guide our efforts across five focus areas in which we plan to set goals and track progress. This strategy codifies the work we are doing to go beyond development of medicines to meet the needs of a global population and create a more equitable and sustainable world.

Expected Milestones

BRUKINSA

- Present clinical data from the global Phase 2 ROSEWOOD trial (NCT03332017) in R/R follicular lymphoma and long-term follow-up results from the Phase 3 ASPEN trial (NCT03053440) of zanubrutinib vs ibrutinib in patients with WM at the 2022 ASCO annual meeting;
- Continue to support ongoing FDA review of the supplemental new indication submission for CLL/SLL, which has a PDUFA target action date of October 22, 2022;
- Continue to support the EMA review of new indication applications for CLL and MZL;
- Announce final analysis data for the global Phase 3 ALPINE trial (NCT03734016) including progression-free survival in the second half of 2022; and
- Continue to expand BRUKINSA's registration program globally in new geographies and indications, including potential launches in 2022 in more than 10 markets.

Tislelizumab

- Continue to support China NMPA review of BLA submission for tislelizumab as a first-line treatment for patients with recurrent or metastatic NPC;
- In collaboration with Novartis, continue to support the EMA review of MAAs for tislelizumab in first-line and second- and third-line NSCLC and second-line ESCC;
- Continue to support additional planned BLA filings by Novartis in first-line NPC in the U.S. and in NSCLC in the U.S. in 2022;
- In collaboration with Novartis, continue to support the ongoing FDA review of the BLA submission in second-line ESCC, with a target PDUFA date of July 12, 2022, subject to completion of regulatory inspections which may be delayed due to COVID-19 restrictions; and
- Announce topline results from the global Phase 3 clinical trial (NCT03412773) of tislelizumab as first-line treatment for patients with hepatocellular carcinoma (HCC) in 2022.

Ociperlimab

- Initiate additional pivotal clinical trials in 2022; and
- Announce data from Phase 1 trial (NCT04047862) cohorts in various solid tumor types in the second half of 2022.

Pamiparib

- Report topline results from the Phase 3 trial (NCT03519230) in China of pamiparib as a maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer in 2022.

BGB-11417 (BCL-2)

- Initiate pivotal trials in the second half of 2022;
- Present Phase 1 clinical data for non-hodgkin lymphoma (NHL), acute myeloid leukemia and CLL (NCT04277637 and NCT04771130) at a medical congress in the second quarter of 2022; and
- Present additional Phase 1 data in late 2022.

Early-Stage Programs

- Initiate dose expansion in the Phase 1 clinical trial (NCT04215978) of BGB-A445 (OX-40) in patients with advanced solid tumors in the first half of 2022;
- Initiate tumor specific expansions for BGB-15025, an investigational HPK1 inhibitor, in combination with tislelizumab in 2022; and
- In collaboration with Leads Biolabs, initiate patient dosing of LBL-007, a novel investigational antibody targeting the LAG-3 pathway in combination with tislelizumab and surzebiclimab (TIM3) in 2022.

Zanidatamab

- In collaboration with Zymeworks, announce efficacy and safety results from HERIZON-BTC-01 (NCT04466891) by early 2023.

COVID-19 Impact and Response

We expect that the worldwide health crisis of COVID-19 will continue to have a negative impact on our operations, including commercial sales, regulatory interactions, inspections, filings, manufacturing, and clinical trial recruitment, participation, and data read outs. There remains uncertainty regarding the future impact of the pandemic both globally and specifically in China due to outbreaks and restrictions and potential impact on clinical, manufacturing and commercial operations. We are striving to minimize delays and disruptions, have put protocols and procedures in place, and continue to execute on our commercial, regulatory, manufacturing, and clinical development goals globally.

BeiGene

Exhibit 99.1

Financial Summary

Select Condensed Consolidated Balance Sheet Data (U.S. GAAP)

(Amounts in thousands of U.S. Dollars)

	As of	
	March 31, 2022	**December 31, 2021**
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 6,252,233	$ 6,624,849
Accounts receivable, net	190,800	483,113
Property and equipment, net	624,673	587,605
Total assets	8,021,388	8,645,949
Liabilities and equity:		
Accounts payable	236,915	262,400
Accrued expenses and other payables	385,976	558,055
Deferred revenue	368,027	407,703
R&D cost share liability	368,543	390,362
Debt	608,992	629,678
Total liabilities	2,135,888	2,402,962
Total equity	$ 5,885,500	$ 6,242,987

BeiGene

Exhibit 99.1

Condensed Consolidated Statements of Operations (U.S. GAAP)

(Amounts in thousands of U.S. dollars, except for shares, American Depositary Shares (ADSs), per share and per ADS data)

	Three Months Ended March 31,	
	2022	**2021**
	(Unaudited)	
Revenue:		
Product revenue, net	$ 261,573	$ 106,117
Collaboration revenue	45,053	499,755
Total revenues	306,626	605,872
Expenses:		
Cost of sales - products	65,237	32,685
Research and development	389,915	320,726
Selling, general and administrative	294,573	182,106
Amortization of intangible assets	188	188
Total expenses	749,913	535,705
(Loss) income from operations	(443,287)	70,167
Interest income (expense), net	10,071	(4,179)
Other income (loss), net	11,967	(4,123)
(Loss) income before income taxes	(421,249)	61,865
Income tax expense (benefit)	13,025	(4,630)
Net (loss) income	(434,274)	66,495
Net (loss) income per share attributable to BeiGene, Ltd.:		
Basic	$ (0.33)	$ 0.06
Diluted	$ (0.33)	$ 0.05
Weighted-average shares outstanding:		
Basic	1,332,017,262	1,188,943,726
Diluted	1,332,017,262	1,257,489,671
Net (loss) income per ADS attributable to BeiGene, Ltd.		
Basic	$ (4.24)	$ 0.73
Diluted	$ (4.24)	$ 0.69
Weighted-average ADSs outstanding:		
Basic	102,462,866	91,457,210
Diluted	102,462,866	96,729,975

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 8,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding clinical data for BeiGene's drug candidates and approvals of its medicines; the conduct of late-stage clinical trials and expected data readouts; additional planned product approvals and launches; the advancement of and anticipated clinical development, regulatory approvals and other milestones and commercialization of BeiGene's medicines and drug candidates; the success of BeiGene's commercialization efforts and revenue growth; the expected capacities and completion dates for the Company's manufacturing facilities under construction; the impact of the COVID-19 pandemic on the Company's clinical development, regulatory, commercial, manufacturing, and other operations; BeiGene's plans and the expected events and milestones under the captions "Recent Business Highlights" and "Expected Milestones"; and BeiGene's plans, commitments, aspirations and goals under the caption "About BeiGene". Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing, commercialization, and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

Investor Contact	**Media Contact**
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ir@beigene.com	media@beigene.com

BeiGene Announces the Approval in China of BLINCYTO® (Blinatumomab) for Injection for Pediatric Patients with Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

CAMBRIDGE, Mass., BASEL, Switzerland & BEIJING — May 4, 2022 — BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that the China National Medical Products Administration (NMPA) has granted conditional approval of BLINCYTO® (blinatumomab) for injection for the treatment of pediatric patients with relapsed or refractory (R/R) CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL). The NMPA granted conditional approval for adult patients in this indication in December 2020.

Developed by Amgen and licensed to BeiGene in China under a strategic collaboration commenced in 2020, this is the second approval for BLINCYTO in China. The pediatric Supplemental Biologic License Application (sBLA) was submitted by BeiGene.

“This approval of BLINCYTO provides us with an opportunity to offer pediatric patients in China with relapsed or refractory B-cell precursor ALL the first approved biospecific immunotherapy treatment option for their disease,” commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China, at BeiGene. “We are proud to be able to offer BLINCYTO to help these young patients as they fight this disease. Our commercial organization of more than 3,100 people in China is excited to add this BLINCYTO indication to our portfolio, which includes 16 approved cancer treatments.”

BLINCYTO for injection for the treatment of adult patients with R/R CD19-positive B-cell precursor ALL was approved conditionally based on ex-China data and interim analysis results of the Phase 3 clinical trial of adult patients in China (NCT03476239). This conditional approval in pediatric patients with the above indication was granted based on ex-China research data and Chinese adult data. The full approval in this indication will depend on the results of a post-marketing study in China.

About Acute Lymphoblastic Leukemia (ALL)
Acute lymphoblastic leukemia (ALL), also known as acute lymphocytic leukemia, is a rapidly progressing cancer of the blood and bone marrow that occurs in both adults and children[1]. ALL accounts for approximately 20% of all adult leukemia, and in China there were an estimated 82,607 new cases of leukemia in 2018[2,3]. In children, the relapse rate of ALL is nearly 10%, while in adults the relapse rate is closer to 50%[4].

About BLINCYTO® (blinatumomab)
BLINCYTO is a BiTE® (bispecific T-cell engager) immuno-oncology therapy that targets CD19 surface antigens on B cells. BiTE molecules fight cancer by helping the body's immune system detect and target malignant cells by engaging T cells (a type of white blood cell capable of killing other cells perceived as threats) to cancer cells. By bringing T cells near cancer cells, the T cells can inject toxins and trigger cancer cell death (apoptosis). BiTE immuno-oncology therapies are currently being investigated for their potential to treat a wide variety of cancers.

BLINCYTO was granted breakthrough therapy and priority review designations by the U.S. Food and Drug Administration and is approved in the U.S. for the treatment of:

- relapsed or refractory CD-19 positive B-cell precursor ALL in adults and children.
- CD-19 positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

In the European Union (EU), BLINCYTO is indicated as monotherapy for the treatment of:

- adults with Philadelphia chromosome negative CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukemia (ALL). Patients with Philadelphia chromosome positive B-precursor ALL should have failed treatment with at least 2 tyrosine kinase inhibitors (TKIs) and have no alternative treatment options.
- adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
- pediatric patients aged 1 year or older with Philadelphia chromosome negative CD19 positive B-precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation
- pediatric patients aged 1 year or older with high-risk first relapsed Philadelphia chromosome negative CD19 positive B-precursor ALL as part of the consolidation therapy.

In China, BLINCYTO is indicated for the treatment of adult patients with relapsed or refractory B-cell precursor ALL.

Important U.S. Safety Information

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES

- **Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® and treat with corticosteroids as recommended.**
- **Neurological toxicities, which may be severe, life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® as recommended.**

Contraindications

BLINCYTO® is contraindicated in patients with a known hypersensitivity to blinatumomab or to any component of the product formulation.

Warnings and Precautions

- Cytokine Release Syndrome (CRS): CRS, which may be life-threatening or fatal, occurred in 15% of patients with R/R ALL and in 7% of patients with MRD-positive ALL. The median time to onset of CRS is 2 days after the start of infusion and the median time to resolution of CRS was 5 days among cases that resolved. Closely monitor and advise patients to contact their healthcare professional for signs and symptoms of serious adverse events such as fever, headache, nausea, asthenia, hypotension, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased total bilirubin (TBILI), and disseminated intravascular coagulation (DIC). The manifestations of CRS after treatment with BLINCYTO® overlap with those of infusion reactions, capillary leak syndrome, and hemophagocytic histiocytosis/macrophage activation syndrome. If severe CRS occurs, interrupt BLINCYTO® until CRS resolves.

Discontinue BLINCYTO® permanently if life-threatening CRS occurs. Administer corticosteroids for severe or life-threatening CRS.

- Neurological Toxicities: Approximately 65% of patients receiving BLINCYTO® in clinical trials experienced neurological toxicities. The median time to the first event was within the first 2 weeks of BLINCYTO® treatment and the majority of events resolved. The most common (≥ 10%) manifestations of neurological toxicity were headache and tremor. Severe, life–threatening, or fatal neurological toxicities occurred in approximately 13% of patients, including encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. Manifestations of neurological toxicity included cranial nerve disorders. Monitor patients for signs or symptoms and interrupt or discontinue BLINCYTO® as outlined in the PI.
- Infections: Approximately 25% of patients receiving BLINCYTO® in clinical trials experienced serious infections such as sepsis, pneumonia, bacteremia, opportunistic infections, and catheter-site infections, some of which were life-threatening or fatal. Administer prophylactic antibiotics and employ surveillance testing as appropriate during treatment. Monitor patients for signs or symptoms of infection and treat appropriately, including interruption or discontinuation of BLINCYTO® as needed.
- Tumor Lysis Syndrome (TLS), which may be life-threatening or fatal, has been observed. Preventive measures, including pretreatment nontoxic cytoreduction and on-treatment hydration, should be used during BLINCYTO® treatment. Monitor patients for signs and symptoms of TLS and interrupt or discontinue BLINCYTO® as needed to manage these events.
- Neutropenia and Febrile Neutropenia, including life-threatening cases, have been observed. Monitor appropriate laboratory parameters (including, but not limited to, white blood cell count and absolute neutrophil count) during BLINCYTO® infusion and interrupt BLINCYTO® if prolonged neutropenia occurs.
- Effects on Ability to Drive and Use Machines: Due to the possibility of neurological events, including seizures, patients receiving BLINCYTO® are at risk for loss of consciousness, and should be advised against driving and engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery while BLINCYTO® is being administered.
- Elevated Liver Enzymes: Transient elevations in liver enzymes have been associated with BLINCYTO® treatment with a median time to onset of 3 days. In patients receiving BLINCYTO®, although the majority of these events were observed in the setting of CRS, some cases of elevated liver enzymes were observed outside the setting of CRS, with a median time to onset of 19 days. Grade 3 or greater elevations in liver enzymes occurred in approximately 7% of patients outside the setting of CRS and resulted in treatment discontinuation in less than 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase, and TBILI prior to the start of and during BLINCYTO® treatment. BLINCYTO® treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if TBILI rises to > 3 times ULN.
- Pancreatitis: Fatal pancreatitis has been reported in patients receiving BLINCYTO® in combination with dexamethasone in clinical trials and the post-marketing setting. Evaluate patients who develop signs and symptoms of pancreatitis and interrupt or discontinue BLINCYTO® and dexamethasone as needed.
- Leukoencephalopathy: Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO®, especially in patients previously treated with cranial irradiation and antileukemic chemotherapy.
- Preparation and administration errors have occurred with BLINCYTO® treatment. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).

- Immunization: Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of BLINCYTO® treatment, during treatment, and until immune recovery following last cycle of BLINCYTO®.
- Risk of Serious Adverse Reactions in Pediatric Patients due to Benzyl Alcohol Preservative: Serious and fatal adverse reactions including "gasping syndrome," which is characterized by central nervous system depression, metabolic acidosis, and gasping respirations, can occur in neonates and infants treated with benzyl alcohol-preserved drugs including BLINCYTO® (with preservative). When prescribing BLINCYTO® (with preservative) for pediatric patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO® (with preservative) and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known. Due to the addition of bacteriostatic saline, 7-day bags of BLINCYTO® solution for infusion with preservative contain benzyl alcohol and are not recommended for use in any patients weighing < 22 kg.

Adverse Reactions

- The most common adverse reactions (≥ 20%) in clinical trial experience of patients with MRD-positive B-cell precursor ALL (BLAST Study) treated with BLINCYTO® were pyrexia (91%), infusion-related reactions (77%), headache (39%), infections (pathogen unspecified 39%), tremor (31%), and chills (28%). Serious adverse reactions were reported in 61% of patients. The most common serious adverse reactions (≥ 2%) included pyrexia, tremor, encephalopathy, aphasia, lymphopenia, neutropenia, overdose, device related infection, seizure, and staphylococcal infection.
- The most common adverse reactions (≥ 20%) in clinical trial experience of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL (TOWER Study) treated with BLINCYTO® were infections (bacterial and pathogen unspecified), pyrexia, headache, infusion-related reactions, anemia, febrile neutropenia, thrombocytopenia, and neutropenia. Serious adverse reactions were reported in 62% of patients. The most common serious adverse reactions (≥ 2%) included febrile neutropenia, pyrexia, sepsis, pneumonia, overdose, septic shock, CRS, bacterial sepsis, device related infection, and bacteremia.
- Adverse reactions that were observed more frequently (≥ 10%) in the pediatric population compared to the adults with relapsed or refractory B-cell precursor ALL were pyrexia (80% vs. 61%), hypertension (26% vs. 8%), anemia (41% vs. 24%), infusion-related reaction (49% vs. 34%), thrombocytopenia (34% vs. 21%), leukopenia (24% vs. 11%), and weight increased (17% vs. 6%).
- In pediatric patients less than 2 years old (infants), the incidence of neurologic toxicities was not significantly different than for the other age groups, but its manifestations were different; the only event terms reported were agitation, headache, insomnia, somnolence, and irritability. Infants also had an increased incidence of hypokalemia (50%) compared to other pediatric age cohorts (15-20%) or adults (17%).

Dosage and Administration Guidelines

- BLINCYTO® is administered as a continuous intravenous infusion at a constant flow rate using an infusion pump which should be programmable, lockable, non-elastomeric, and have an alarm.
- It is very important that the instructions for preparation (including admixing) and administration provided in the full Prescribing Information are strictly followed to minimize medication errors (including underdose and overdose).

Please see full Prescribing Information and medication guide for BLINCYTO at www.BLINCYTO.com.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 8,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the commercialization and potential benefits of BLINCYTO®; and BeiGene's plans and expectations for the commercialization of its and Amgen's other oncology products and pipeline assets. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

BLINCYTO® and BiTE® are registered trademarks of Amgen Inc.

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